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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/790,540	01/30/1997	WILLIAM D. HUSE	P-IX-2405	1555

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	25

DATE MAILED: 02/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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08/790540

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 9/17/01; 11/20/01

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-32 is/are pending in the application.
Of the above, claim(s) 19-25 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-18, 26-32 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

DETAILED ACTION

1. Applicant's amendment, filed 9/17/01 (Paper No. 32) and 11/20/01 (Paper No. 34) , have been entered. Claim 32 has been added.

Claims 1-18 and 26-32 are under consideration in the instant application.

Claims 19-25 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. The rejections of record can be found in previous Office Actions (Paper Nos. 5/8/13/16/20/25/29).

Applicant's arguments and the examiner's rebuttal are essentially the same of record.
A more thorough review of applicant's arguments and the examiner's rebuttal of record can be found in Paper No. 29 or reiterated herein for applicant's convenience.

3. Claims 1, 2, 9,10, 12-18 and newly added claim 32 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "having 88% / 79% or greater identity

Applicant's arguments in conjunction with certain legal decisions, filed 9/17/01 (Paper No. 32), were fully considered and not found convincing for the reasons of record set forth in Paper Nos. 20/25/29.
Applicant's arguments and the examiner's rebuttal are essentially the same of record

While it is acknowledged that the claims have been amended from "having greater than 88% / 79% identity" to "having 88% / 79% or greater identity"; the issues are the same.

Again, applicant's amendment, filed 9/1/01 (Paper No. 32), directs support to pages 45 - 48 and to various other passages in the specification as-filed for these above-mentioned "limitations". Applicant relies upon the teaching of the specification (e.g. pages 20-21) disclosing methods that can be used to change any or all of the non-identical amino acids either alone or in combination. Applicant asserts that the ordinary artisan would have understood that the substitution of any, but less than all of the amino acids would have resulted in the claimed limitations.

As pointed out previously, while the specification as filed provides for 'CL had "88/79%" identity to frameworks 1, 2 and 3 of LM609 heavy chain/light chain; there is insufficient written description for " and greater" as well as "at least one LM609 CDR-grafted heavy/light chain polypeptide comprising a variable region amino acid sequence greater than 88%/79% identity with that shown in Figure 1A/1B" or "functional fragments" thereof, or "nucleic acids" encoding the same; as currently recited..

The specification as filed does not provide sufficient written description for these newly claimed limitations", as they are currently recited. Applicant's reliance on generic disclosure and possibly a single species does not provide sufficient direction and guidance to the "currently claimed limitations". It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it. Also, see MPEP 2163.05 Changes to the Scope of Claims.

It appears that applicant acknowledges that these particular "terms and phrases" do not have written description in the specification as filed; therefore the claims represent a departure from the specification and claims as originally filed. Applicant's reliance on generic disclosure and possibly a single or limited species do/does not provide sufficient direction and guidance to the "features" currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Again, applicant is invited to provide sufficient written support for the "limitations" indicated above.

Applicant's arguments are not found persuasive

4. Claims 1-18, 26-31 and newly added claim 32 are rejected under 35 U.S.C. § 102(f) because the applicants did not invent the claimed subject matter.

As pointed out previously; applicant's arguments, in conjunction with the Huse declaration have been as well as U.S. Patent No. 5,753,230 (1449) and Biotechnology Newswatch Biotechnology Newswatch (1/16/95) presented an ambiguity with regard to the inventorship of the claimed invention.

Applicant's arguments in conjunction with certain legal decisions have been fully considered but are not found convincing essentially for the reasons of record.

Applicant maintains that the inventorship has been reviewed and determined to be correct and that both Huse and Glaser have been determined to be inventors of the claimed compositions, wherein the claimed compositions have specifically recited SEQ ID NOS..

As pointed out previously; it was noted that the Huse Declaration, filed 12/14/98 (Paper No. 12) indicates that he conceived the idea of humanizing $\alpha_v\beta_3$ inhibitory antibodies.

It is noted that the Huse/Glaser Declaration under 37 C.F.R. § 1.132, filed 6/12/00 (Paper No. 23), states that both Huse and Glaser are joint inventors of the instant claims

Huse avers in the Declaration that the sequences of the claimed antibodies and encoding nucleic acids were not known prior to cloning and sequencing of the LM609 heavy and light chain variable region and generation of LM609 grafted antibodies at Ixsys. The Declaration states that the LM609 hybridoma was brought to Ixsys, Inc., where the LM609 heavy and light chain variable region cDNA was cloned.

Applicant argues that conception of the claimed compositions having specifically recited SEQ ID NOS requires the determination of the nucleotide sequence of the LM609 heavy and light chain variable regions and the use of determined sequences to generate the claimed grafted antibodies having specifically recited SEQ ID NOS.

Applicant asserts that the Declaration indicates that neither Cheresh nor Brooks suggested or contributed to the cloning, sequencing, humanizing or making the claimed antibodies and nucleic acids.

Applicant has maintained that Cheresh and Brooks could be considered, at most, technical collaborator but not an inventor of the claimed antibodies and nucleic acids referenced as specifically recited SEQ ID NOS.

The test for conception is whether inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; an idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand; and it must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. For example, see Burroughs Wellcome Co. v. Barr Laboratories Inc. 32 USPQ2d 1915 (CAFC 1994).

However, applicant has not provided sufficient objective evidence or information to address either the contribution of Glaser to the claimed invention, given the first Huse Declaration, filed 12/14/98 (Paper No. 12), which indicated that he alone conceived the idea of humanizing $\alpha_v\beta_3$ inhibitory antibodies or the contribution of Cheresh as a scientific collaborator, but not as an inventor.

Again, as pointed out previously, applicant has not provided the facts concerning the nature and role of Cheresh as a collaborator, with respect to humanizing the LM609 antibody. It is noted that Biotechnology Newswatch acknowledges that Cheresh was the principal investigator. It is clear that Cheresh developed the LM609 antibody and that it was possible to determine without undue experimentation antibodies and humanized antibodies having the same properties (see U.S. Patent No. 5,753,230, particularly columns 15-19). Further, U.S. Patent No. 5,753,230 claims the use of LM609 antibody as well as humanized versions thereof. Similarly the instant specification acknowledges that Cheresh developed the LM609 antibody (see page 9, for example) and that generating humanized/CDR-grafted antibodies were known in the art at the time the invention was made (see page 17, for example). Again, it is clear that given U.S. Patent No. 5,753,230 that humanizing $\alpha_v\beta_3$ inhibitory antibodies, including the LM609 antibody was known in the prior art by others. Again, it is noted that Brooks was an inventor on U.S. Patent No. 5,753,230.

Also, it is noted that Huse and Glaser are listed as inventors of the pending claims of copending USSN 08/791,391.

As pointed out previously, the arguments of counsel cannot take the place of evidence in the record. In re Schulze 346 F.2d 600, 502; 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

To resolve the ambiguity, applicants may file declarations by the non-applicant(s) Cheresh (and Brooks) disclaiming the invention or a declaration by applicant setting forth the facts which provide an explanation as to why the non-applicant are not inventors. Further, applicant may provide facts why Glaser is an inventor.

Applicant's arguments are not found persuasive.

5. Claim 26 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Brooks et al. (U.S. Patent No. 5,753,230) essentially for the reasons of record set forth in Paper Nos. 16/20/25/29.

Applicant's arguments in conjunction with the Huse declaration under 37 C.F.R. § 1.132 of record, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that to anticipate a claim, the reference must teach every element of the claim and that absent a teaching of the structural features other antibody specifically recited in the claims as SEQ ID NOS: 1 and 3; the rejection of record should be withdrawn.

Given that claim 26 recites "of a modification thereof or a functional fragments of said LM609 CDR-grafted antibody" and the prior art teaching of humanized LM609 antibodies; applicant's arguments concerning the particular structural characteristics of the claimed limitations have not been found persuasive. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed "limitations" read on "modifications thereof or a functional fragments of said LM609 CDR-grafted antibody"

Applicant's arguments relying upon the particular SEQ ID NOS: recited in claim 26 does not obviate the prior art teaching, as it reads on "a modification thereof or a functional fragments of said LM609 CDR-grafted antibody" of the same LM609 antibody of the claimed invention.

Applicant's arguments are not found persuasive.

6. Claims 1-18 and 26-31 and newly added claim 32 rejected under 35 U.S.C. § 103 as being unpatentable over Brooks et al. (U.S. Patent No. 5,753,230; 1449) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 3-37 or Examples I and II of the instant specification or as cited by references on the 1449 for the reasons of record set forth in Paper Nos. 16/20/25/29.

The teachings of Brooks et al. in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 10-39 or Examples I and II of the instant specification or as cited by references on the 1449 are of record. Briefly, teach the LM609 antibody as well as humanized forms of this antibody and claim methods of using the LM609 antibody as well as humanized forms of this antibody (see entire document, particularly columns 15-19 and the claims). With respect to specific amino acid changes including those which are "modifications" would be obvious given the teachings of humanized LM609 antibodies and art known methods to generate such humanized antibodies which retain the desired functional characteristics of the native antibody and to alter said antibody for therapeutic uses, including human therapy, as taught and known in the prior art.

Applicant's arguments in conjunction with the Huse/Glaser declarations under 37 C.F.R. § 1.132 of record have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same as of record, which are reiterated herein for applicant's convenience.

Again applicant arguments have essentially focused on whether the prior art taught the particular structural features of the LM609 antibody, particularly the nucleic acid or amino acid sequences of the LM609 antibody. Applicant argues that the prior art teaching does not teach or suggest the claimed compositions having specifically recited SEQ ID NOS.

Applicant has argued that the claims recite structural characteristics which are not taught or suggested in any of the cited references. Applicant has argued that Brooks et al. do not teach or suggest the claimed human acceptor framework sequences LM609 CDR's, encompassed by SEQ ID NOS: 2, 3, 32, including the amino acid at position 49. Applicant asserts that the change of amino acid to three other amino acids unexpectedly results in functional antibody having integrin $\alpha v\beta 3$ binding activity.

Applicant has argued in conjunction with Deuel that the prior art, including Brooks et al. does not teach nor suggest the nucleic acids having the structural characteristics of the specifically recited SEQ ID NOS.

Applicant has argued that the prior art describes the mouse antibody and not applicant's claimed non-mouse antibodies having human acceptor framework sequences with LM609 CDR's

Applicant has argued that Padlan teaches away from the claimed invention.

Applicant has argued in conjunction with the Huse Declaration that there were difficulties in cloning authentic DNA sequences.

The following is provided for applicant's convenience.

As pointed out previously; the amino acid and nucleic acid sequences associated with the LM609 antibody including those of humanized LM609 antibodies would have been available to the ordinary artisan, given the availability of the LM609 antibody and hybridoma together with general immunoglobulin gene cloning and expression strategies. It would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate chimeric or humanized LM609 antibodies, DNA encoding said antibodies. Given the highly conserved nature of immunoglobulin gene organization and structure and the availability of probes and PCR primers for immunoglobulin gene cloning, one of ordinary skill in the art could have isolated the functionally rearranged heavy and light chain variable regions from the LM609 hybridoma cell line and determined their sequences with a complete expectation of success. For example, the ordinary artisan does not need to determine the amino acid sequences of a rearranged V (variable) region before cloning. The claims do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected to obtain given the known LM609 hybridoma thereof, the known heavy and light chain and the art known techniques regarding the production of chimeric antibodies, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement. The claimed DNA sequences must encode a recombinant antibody comprising heavy and/or light chain variable regions of the LM609 antibody.

Immunoglobulin gene structure and organization were well understood in the art a the time the claimed invention was made and that strategies for cloning the DNAs encoding immunoglobulin variable regions genes were well established in the art at the time the claimed invention was made, as were methods for the production of DNA constructs encoding immunoglobulin variable regions. In addition, it was known at the time the invention was made that the benefits of producing recombinant antibodies to reduce the immunogenicity of therapeutic and diagnostic antibodies in human patients. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

As pointed out in the previous Office Actions, it was noted that the instant disclosure relied upon standard humanization procedures to derive the claimed antibody and nucleic acid compositions. Also, it was noted that Biotechnology Newswatch (1/16/95 and 2/6/95) references above support the routine nature of providing an antibody/hybridoma of interest to a commercial interest to develop humanized antibodies and the nucleic acids encoding said antibodies by routineers in the art at the time the invention was made.

In contrast to applicant's assertions and for the reasons of record and reiterated above; the claimed antibodies and nucleic acids do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected given the availability of the LM609 antibody and hybridoma in the prior art as well as the art known techniques regarding the production of chimeric and humanized antibodies at the time the invention was made, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement.

For example, page 15, paragraph 1 of the specification discloses that functional replacement of the CDRs was performed by recombinant methods known to those skilled in the art, commonly referred to as CDR grafting. Also, page 20, paragraph 1 of the specification discloses that identification of amino acids to be changed can be accomplished by those skilled in the art using current information available regarding the structure and function of antibodies as well available and current information encompassing methods for CDR grafting procedures. In addition, page 20, paragraph 2 of the specification discloses using the above described methods known within the art, any or all of the non-identical amino acids can be changed either alone or in combination with amino acids at different positions to incorporate the desired number of amino acid substitutions at each of the desired positions. Page 21, paragraph 1 discloses that the functional replacement of amino acids is beneficial when producing grafted antibodies having human framework sequences since it allows for the rapid identification of equivalent amino acid residues without the need for structural information or the laborious procedures necessary to assess and identify which amino acid residues should be considered for substitution in order to successfully transfer binding function from the donor. Also see (Singer et al., J. Immunol. 150: 2844-2857, 1993 and Padlan, Mol. Immunol 28: 489-498, 1991 of the Information Disclosure Statement; which provide for art known procedures and expectation of success in humanizing known antibodies of interest, including deriving the appropriate changes to derive the desired reduction in reduced immunogenicity and in desired specificity. The claimed grafted antibodies and associated nucleic acids were predictable by the known and practiced means (e.g. computer modeling) at the time the invention was made. It is noted that Padlan discloses the same procedures using the same frameworks in procedures for reducing the immunogenicity of antibody variable domains while preserving their ligand-binding properties as relied upon in applicant's claimed invention (see entire document).

Therefore, it appears that applicant has relied upon the same starting material as the prior art (LM609 antibody and hybridoma) and that applicant has relied upon the same recombinant means to derive the same antibodies and nucleic acids derived from humanizing the LM609 antibody taught and claimed by the prior art. It is clear that Brooks et al. teach antibodies that have the same or similar immunoreactive characteristics and compete for binding to the same preselected target molecule as the LM609 antibody (see columns 15-18, particularly column 17). In contrast to applicant's assertions; humanizing the LM609 antibody or modifying humanized LM609 antibody and its associated nucleic acids in achieving the claimed limitations was known and obvious, given the same starting materials, including the LM609 antibody/hybridoma and acceptor molecules and given the same recombinant means to achieve the same humanized antibodies as clearly taught and known in the prior art. As pointed out above, the modifications other than simple CDR-grafted LM609 antibody appear to be predictable or to be predicated on the same standard and known computer modeling in the prior art in humanizing antibodies of interest.

Also as pointed out above, for examination purposes under art; the recitation of 'a modification thereof that does not change the encoded amino acid sequence" reads on modifications which do not change the encoded amino acid sequence due to the degeneracy of the genetic codes as well as those which result in only a conservative substitution of the encoded amino acid sequence. Such modifications would have resulted in humanized LM609-specific antibodies encompassed by the claimed invention.

Also, the claims recited functional fragments thereof and again; such limitations would have been obvious in view of the prior art teaching of generating humanized LM609-specific antibodies.

Applicant's arguments are not found persuasive.

7. Claims 1-18, 26-31 and newly added claim 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 15-26, 33-42 and 56-57 of copending application USSN 08/791,391 essentially for the reasons of record.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Again, applicant's amendment, filed 9/17/01 (Paper No. 32), request that this provisional ground of rejection be deferred until there is an indication of allowable subject matter

Applicant has provided for the common ownership of the instant application with USSN 08/791,391.

8. Claims 1-18, 26-31 and newly added claim 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 56-97 (or appropriate pending claims) of copending USSN 09/016,061 and

claims 1-20 and 25-33 (or appropriate pending claims) of copending USSN 09/339,922.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims appear to be drawn to similar or obvious variants of LM609-specific humanized antibodies, fragments and nucleic acids encoding said antibodies/fragments thereof .

It is acknowledged that certain LM609-specific modifications of USSN 09/016,061 and USSN 09/339,922 may be considered distinct species from the instant claims.

However, it is noted that SEQ ID NOS: 3,5,6 and 32 of USSN 09/016,061 and SEQ ID NOS: 3,4,5,6,31 and 32 of USSN 09/339,922 appear to read on the instant claims.

Applicant is invited to distinguish the pending claims from one another.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-18, 26-31 and newly added claim 32 are directed to an invention not patentably distinct from claims 56-97 of copending USSN 09/016,061 and
claims 1-20 and 25-33 of copending USSN 09/339,922.

Specifically, the conflicting claims are patentably distinct from each other because the pending claims are drawn similar or obvious variants of LM609-specific humanized antibodies, fragments and nucleic acids encoding said antibodies/fragments thereof.

It is acknowledged that certain LM609-specific modifications of USSN 09/016,061 and USSN 09/339,922 may be considered distinct species from the instant claims.

However, it is noted that SEQ ID NOS: 3, 5, 6 and 32 of USSN 09/016,061 and SEQ ID NOS: 3,4,5,6,31 and 32 of USSN 09/339,922 appear to read on the instant claims.

Again, applicant is invited to distinguish the pending claims from one another.

Commonly assigned USSNs 09/016,061 and 09/339,922, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

10. No claim is allowed.